COMMONWEALTH OF VIRGINIA
Department of Environmental Quality
Valley Regional Office

STATEMENT OF LEGAL AND FACTUAL BASIS

Merck & Co., Inc.
Rockingham County, Virginia
Permit No. VRO80524

Title V of the 1990 Clean Air Act Amendments required each state to develop a permit program to ensure that certain facilities have federal Air Pollution Operating Permits, called Title V Operating Permits. As required by 40 CFR Part 70 and 9 VAC 5 Chapter 80, Merck & Co., Inc., has applied for a renewal of its Title V Operating Permit for its Rockingham County pharmaceuticals production facility. The Department has reviewed the application and has prepared a draft Title V Operating Permit.

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FACILITY INFORMATION

Permittee
Merck & Co., Inc.
2778 South East Side Highway
Elkton, Virginia 22827

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Merck & Co., Inc.
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Elkton, Virginia 22827

Plant ID No. 51-165-0001

SOURCE DESCRIPTION

NAICS Code 325412 (formerly SIC Codes 2833 and 2834) – Pharmaceutical preparation manufacturing

Merck & Co., Inc. (Merck) operates a pharmaceutical preparation manufacturing facility in Rockingham County. The plant, originally constructed in the 1940's, includes pharmaceutical production process units (to include storage tanks, reactors, vessels, receivers, etc.), a storage tank farm, wastewater treatment facility, and a powerhouse (including two natural gas-fired boilers having one fuel oil-fired backup boiler). The plant produces various pharmaceutical intermediates and products.

The facility is a PSD major source of volatile organic compounds (VOC), nitrogen oxides (NO_x), and sulfur dioxide (SO_2) and a synthetic minor source of hazardous air pollutants (HAPs). The source is located in an attainment area (Rockingham County) for all regulated pollutants. The facility is located approximately two kilometers from a PSD Class I area (Shenandoah National Park (SNP)). Merck operates under a Project XL permit dated January 7, 1998 and administratively modified August 8, 2001 and modified xx/xx/xx. Merck's initial Title V permit was issued October 1, 2001 and expires October 1, 2006. A significant modification to the Title V permit was issued effective October 21, 2002.

COMPLIANCE STATUS

A full compliance evaluation of this facility, including a site visit, was most recently conducted on September 28, 2005. In addition, all reports and other data required by permit conditions or regulations, which are submitted to DEQ, are evaluated for compliance. Performance testing conducted according to the 10/21/02 Title V modified permit indicated control device operation in one factory area that resulted in higher actual HAP emissions than originally calculated. The

subsequent adjustment in calculated HAP emissions indicated an exceedance of the facility's HAP emission limits in the modified Title V permit. Merck has since signed a Consent Order (dated July 5, 2005) with DEQ that includes steps to be taken to return to a compliant status. Compliance reports submitted in accordance with the Order show that Merck is currently in compliance with the HAP limits. A compliance plan having terms at least as stringent as the Consent Order has been incorporated into the Title V renewal permit.

The facility has not been found to be in violation of any other state or federal applicable requirements at this time.

CHANGES SINCE INITIAL PERMIT

During the five-year term of Merck's Title V permit, the permit was modified once to establish synthetic minor HAP limits for the facility. The modified permit limits emissions of HAPs across the site to 9.9 tons/year (individual HAP) and 24.9 tons/year (combined HAPs). Supporting documentation for the Title V modification is included in the Statement of Legal and Factual Basis for the modification, dated October 21, 2002.

In addition to the significant modification, the following changes were made to equipment at the facility during the five-year term of the Title V permit and are included in the draft renewed Title V permit:

- *Sludge incinerator shutdown:* The sludge incinerator has been permanently shutdown. A Mutual Shutdown Determination for the incinerator is on file at Valley Regional Office (VRO). All reference to the incinerator has been removed from the Title V renewal permit, including former Section V of the permit.

- *Installation of new RTO:* A new regenerative thermal oxidizer (RTO) (RE-3501) has been installed in the Carbidopa production area to replace the unit designated RE-3500. Reference to RE-3500 has been replaced throughout the permit by RE-3501.

- *Completion of required stack testing:* Merck has completed the performance testing of designated HAP control devices (various scrubbers and an oxidizer) required by Condition IV.D.1 of the current Title V permit. The condition has been removed from the Title V renewal draft permit.

- *Control of equalization tank 121:* A fixed roof cover has been installed on equalization tank 121 (TA-121) in the wastewater treatment facility, in accordance with Condition IV.A.5 of the Title V permit. A slight change has been made to the condition to require ongoing control of the unit by fixed-rood cover.

- *New process: Dorzolamide:* On April 1, 2006, Merck commenced production of Dorzolamide, a product previously manufactured at another Merck plant. The new process employs existing equipment in the Factory 2 area (also used to manufacture

Indinavir and MK-476 (Montelukast)) as well as some new equipment. On May 17, 2006, VRO received the notification of the new process as required by Condition IV.E.4 of the Title V permit. No new applicable requirements were triggered by the new process.

- *Insignificant activities list (Permit Attachment A) revision:* Following commencement of the Dorzolamide process, the uncontrolled particulate emissions of certain units increased such that they no longer meet the insignificant activities criteria in 9 VAC 5 Chapter 80, Article 4. Accordingly, the units have been removed from the Insignificant Activities List (Permit Attachment A) and will be subject to periodic visible emissions monitoring required by Condition IV.B.2 of the current permit.

- *Carbidopa control device changes:* In accordance with Item 1 of the 7/5/05 CO, adjustments have been made to certain control devices serving the Carbidopa process, to ensure maintenance of proper control efficiency. The changes, including identification of appropriate parameters to be monitored, a range of values for such parameters, and the requirement to monitor and record the parameters have been made enforceable by inclusion in the Title V renewal draft permit (see Compliance Plan (Section VIII) of draft renewal permit).

In addition to the changes noted above, the renewal permit includes the following changes in the permit text:

- *XL PSD permit revisions:* Merck's Project XL PSD permit requires a five-year periodic review by the stakeholders to assess the adequacy of the permit's monitoring, recordkeeping, and reporting requirements and to review the need for other changes to the permit that have been noted during the previous five years. The first five-year review meeting was held July 28, 2005 and resulted in several proposed changes to the XL permit. The XL permit is being modified under 9 VAC 5 Chapter 190 to incorporate the changes agreed to by the stakeholders. The XL permit modification is being processed and public notice is being provided concurrently with the Title V renewal permit. The XL permit is incorporated into the Title V permit and the Title V renewal permit reflects the recent changes to the XL permit agreed to by the stakeholders. The changes include: modifying the monitoring provisions such that more stringent monitoring may be triggered by actual emissions of individual pollutants (SO_2 and NO_x), not only by actual total emissions; extension of due date for monthly emissions calculations from one month to two months after the end of each rolling 12-month period; allowance for Title V-required HAP monitoring to constitute compliance with the XL permit monitoring provisions for a given control device, where such Title V requirements are more stringent than the XL monitoring provisions; and miscellaneous administrative changes. Further details on the XL permit changes are in the XL permit modification supporting documentation, which is attached.

- *Language facilitating transition to major HAP status:* The renewal permit includes a new section that stipulates that Merck shall become a major source for HAPs (i.e., the HAP limits and associated requirements in Section IV of the permit shall no longer be applicable) on January 1, 2008 and that Merck shall from that day on comply with all applicable provisions of 40 CFR 63 Subpart GGG (National Emission Standards for HAPs for Pharmaceuticals Production). The section further allows Merck to choose to postpone the transition to major-source status, at six-month intervals, by providing a notification of at least 30 days prior to the scheduled major-source transition date.

- *Addition of 40 CFR 63 Subpart GGG requirements:* Process emission, monitoring, recordkeeping, reporting, and testing requirements from the Pharmaceutical MACT, as they apply to Merck's current operations, have been incorporated into the renewal permit. An effective date of January 1, 2008 has been designated. The effective date may be postponed for six-month intervals if Merck provides the notification required in Section V of the draft renewal permit that it chooses to continue to operate under its synthetic minor HAP limits (limits in Section IV of the permit).

- *Compliance Plan:* The Title V renewal permit includes a compliance plan (Section VIII) that is at least as stringent as the requirements from Appendix A of the July 8, 2005 consent order between DEQ and Merck.

- *General conditions:* The "General Conditions" section of the Title V permit has been updated to reflect changes made to the Title V boilerplate since Merck's permit was modified in 2002.

Also, the Inapplicable Requirements section of the permit has been updated to include some federal regulations identified by the applicant as inapplicable. Also, a list of insignificant emissions units according to 9 VAC 5 Chapter 80, Article 4 has been added to the draft renewal permit.

EMISSION UNIT AND CONTROL DEVICE IDENTIFICATION

Equipment to be operated at the facility consists of:

Table 1. General emission unit areas

Emission Unit ID	Emission Unit Description	Applicable Permit Date
B	Powerhouse: - backup distillate oil-fired boiler (4) - natural gas-fired boilers (with distillate oil or propane backup) (7 & 8)	2/10/1998 administratively modified 8/8/2001 modified x/xx/xx
C	Internal Combustion Engines	2/10/1998 administratively modified 8/8/2001 modified x/xx/xx
D	Production Process Units	2/10/1998 administratively modified 8/8/2001 modified x/xx/xx
E	Sludge Dryer	2/10/1998 administratively modified 8/8/2001 modified x/xx/xx

HAP equipment to be operated consists of*:

Table 2. HAP emission units

Emission Unit ID	Stack ID	Emission Unit Description	Size/ Rated Capacity	Pollution Control Device (PCD) Description	PCD ID	Pollutant Controlled	Applicable Permit Date
Carbidopa Process	Unit Ref. 11	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Units	SCR-301, -535, -615/616, 634/3500 & 2546 and TOU-2542 & RE-3501	Hazardous Air Pollutants (HAPs)	N/A
MK-476	Unit Ref. 22	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Unit	SCR-2546 and TOU-2542	HAPs	N/A
Indinavir (Crixivan®)	Unit Ref. 21	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Unit	SCR-2546, 1427/1427A& 301 and TOU-2542	HAPs	N/A
Central Solvent Recovery	Unit Ref. 41-42	Solvent recovery in support of pharmaceutical production processes		Scrubbers and Thermal Oxidation Unit	SCR-1000, TOU-2542/SCR-2546	HAPs	N/A
MK-991	Unit Ref. 81	Pharmaceutical production process equipment		Scrubber	SCR-9050	HAPs	N/A
Primaxin for Recovery	Unit Ref. 75	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Imipenem	Unit Ref. 73	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Cilastatin	Unit Ref. 72	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Sodium Bicarbonate	Unit Ref. 74	Pharmaceutical production process equipment		N/A	N/A	N/A	N/A
Dorzolamide	Unit Ref. 23	Pharmaceutical production process equipment		Scrubbers and Thermal Oxidation Unit	TOU-2542/SCR-2546, SCR-1500	HAPs	N/A
TA-120, TA-121	Unit Ref. F	Wastewater storage tanks		Tank Covers	TA-120 Cover, TA-121 Cover	HAPs	N/A
Misc. Sources	-	Support services for pharmaceutical production process equipment (such as: stationary internal combustion engines, fugitives, lab hoods,		N/A	N/A	N/A	N/A

Emission Unit ID	Stack ID	Emission Unit Description	Size/ Rated Capacity	Pollution Control Device (PCD) Description	PCD ID	Pollutant Controlled	Applicable Permit Date
		boilers, gasoline tanks, and materials used in maintenance, repair, and construction activities, etc.)					

*This table is provided for informational purposes only, and is not an applicable requirement.

EMISSIONS INVENTORY

Emissions for 2005 were reported in Merck's annual emissions update and are summarized in the following table.

Table 3. 2005 actual criteria pollutant emissions

	Criteria Pollutant Emission in Tons/Year				
Emission Unit	**VOC**	**CO**	**SO_2**	**PM_{10}**	**NO_x**
Boilers	0.43	5.06	2.25	1.49	17.83
Pharmaceuticals Production Units	86.08	0.39	0	2.42	1.38
Emergency generators	0.15	1.24	0.18	0.05	1.50
Sludge dryer	0.24	-	-	0.47	-
Total	**86.9**	**6.69**	**2.43**	**4.43**	**20.71**

Table 4. Actual HAP emissions (5/1/05 through 4/30/06)

Hazardous Air Pollutant	**Emissions (tons/yr)**
Acetonitrile (CAS 75-05-8)	1.0
Chlorine (CAS 7782-50-5)	0.2
Cyanide compounds	0
Glycol ethers	0.6
Dimethylformamide (CAS 68-12-2)	0.6
Ethylene glycol (CAS 107-21-1)	0.8
Hydrazine (CAS 302-01-2)	0
Hydrochloric Acid (CAS 7647-01-0)	1.4
Methanol (CAS 67-56-1)	4.4
Methyl chloride (CAS 74-87-3)	1.5
Methyl tert-butyl ether (CAS 1634-04-4)	0.5
Toluene (CAS 108-88-3)	2.3
Triethylamine (CAS 121-44-8)	0.1
Miscellaneous HAPs	0.2

Total HAPs	**13.6**

EMISSION UNIT APPLICABLE REQUIREMENTS

Merck is currently operating under a PSD permit, dated January 7, 1998 (administratively modified 8/8/2001 and modified xx/xx/xx), issued under EPA's Project XL permit program. All section numbers are from the PSD permit; a copy of the permit is included as Attachment B. The Federal and State rulemakings to support the PSD permit can be found in Attachments C and D, respectively.

Facility Wide Conditions (Project XL)

Limitations

Section 1 from the PSD permit (Site-wide Emission Caps) has been incorporated into the Title V permit.

A site-specific provision of 40 CFR 60 Subpart Db (Standards of Performance for Industrial, Commercial and Institutional Steam Generating Units) requires that low NO_x technology be installed on the natural gas-fired boilers in the powerhouse (see 40 CFR 60.49b(u)(1)(i)). This requirement has been incorporated into the Title V permit. Also, the approved fuels for the boilers have been included.

Monitoring and Recordkeeping

The monitoring, recordkeeping, and reporting requirements in Section 4 of the PSD permit have been incorporated and meet Part 70 requirements.

40 CFR 60.49b(u)(1)(ii), a site-specific monitoring requirement in NSPS Subpart Db, requires Merck to operate a continuous emissions monitoring system or a predictive emissions monitoring system for NO_x emissions from the natural gas-fired boilers. This requirement has been incorporated into the Title V permit.

Section 4 of the PSD permit dictates all of the required monitoring, recordkeeping, and reporting requirements for all of the applicable requirements in the permit. A tiered approach is utilized such that the requirements increase as Merck begins to operate at levels closer to the caps. The monitoring and recordkeeping that are in the PSD permit, and have been incorporated into the Title V permit, satisfy the periodic monitoring requirement for all applicable requirements in the permit, according to the state rulemaking that is applicable to Merck (9 VAC 5 Chapter 190, Variance for Merck Stonewall Plant) (see Attachment D). The variance states that the monitoring in the PSD permit satisfies the monitoring requirements in 9 VAC 5-80-110E. Therefore, the monitoring in the Title V operating permit satisfies the periodic monitoring requirements for the facility.

Reporting

The reporting requirements from Section 4 of the PSD permit have been moved into their own section. This will allow Merck and DEQ staff to more easily identify the reporting requirements.

Testing

The permit requires performance testing on certain units when Tier III monitoring/reporting is reached. A table of test methods has been included in the permit if testing is performed. The Department and EPA have authority to require testing not included in this permit if necessary to determine compliance with an emission limit or standard.

Streamlined Requirements

The following Section of the PSD permit was not incorporated into the Title V permit because the requirements have been completed. Please note that section numbers refer to those found in the PSD permit, a copy of which is included as Attachment B.

Sections 1.1 and 1.2.1 – The powerhouse conversion has been completed and therefore the adjustments to allowable emissions required by 1.2.1 are in effect. The initial sitewide caps in 1.1 have been effectively superseded. The Title V renewal permit therefore only shows the adjusted post-powerhouse conversion allowable emissions that are effective.

Sections 2.1, 2.2, 2.3 and 2.4.1 – The powerhouse conversion has been completed, therefore these conditions mandating the schedule for completion and granting preconstruction authorization have been omitted from the Title V permit renewal.

Section 5 - Merck is operating under the emission caps. Therefore, the requirements for phase-in of PSD permit terms have been fulfilled and have not been included in the Title V renewal permit.

Facility Wide Conditions for Hazardous Air Pollutants (HAPs) – Synthetic Minor Operation

Effective October 21, 2002, Merck's Title V permit was modified to establish synthetic minor HAP limits for the facility. The modified permit limits emissions of HAPs across the site to 9.9 tons/year (individual HAP) and 24.9 tons/year (combined HAPs). Supporting documentation for the Title V modification is included in the Statement of Legal and Factual Basis for the modification, dated October 21, 2002.

Limitations

The permit limits sitewide emissions of HAPs to 9.9 tons per year (for each individual HAP) and 24.9 tons per year (all HAPs combined). The limits establish the Stonewall Plant as a synthetic

minor source of HAPs and thereby preclude applicability of standards in 40 CFR 63 (MACT standards).

The permit requires the operation of specified controls for certain production areas as follows:

Carbidopa – thermal oxidation and scrubber control
Unloading of anhydrous hydrogen chloride (HCl) railcar – scrubber control
Indinavir and MK-476 – thermal oxidation and scrubber control
Central Solvent Recovery – scrubber control
MK-991 – scrubber control

The permit also requires that wastewater treatment equalization tanks (TA-120 and TA-121) be controlled by fixed-roof covers to control volatile HAPs.

Monitoring

Stringent monitoring requirements have been established to provide a reasonable assurance of compliance with the synthetic minor HAP limits. The monitoring focuses on the areas of leak detection and repair and control device parameter monitoring.

Leak detection and repair (LDAR) – The permit includes rigorous LDAR requirements that were derived from those in 40 CFR 63 Subpart GGG (Pharmaceuticals MACT). It requires Merck to use site-specific leak emission factors and periodic leak checks to quantify HAP emissions from leaking components. The permit includes a requirement to check for leaks on a tiered schedule, from annually to once every four years, dependant upon leak emission rates. Any leaks detected are required to be repaired within 15 days of detection. The permit requires that Merck adjust its leak emission factors if results of the monitoring indicate that the leak rate has increased. The requirements supplement the existing leak program and serve indirectly to verify the validity of the emission factors. They also ensure that any leaks are repaired in a timely manner and thereby provide reasonable assurance that the factors used to calculate leak emissions are appropriate.

Control device parameter monitoring - For control devices treating streams containing one or more tons per year HAP (individual or in the aggregate), the permit requires frequent monitoring of control device operating parameters. Conditions IV.B.21 through IV.B.25 specify operating parameters indicative of proper performance for each type of control device known to control HAPs at the plant and for which control credit is taken in calculating actual emissions. The permit requires recording of parameter values at a minimum frequency.

The control device monitoring requirements are summarized below:

Table 5. Summary of required monitoring for control devices

Type of control device	Parameter to be monitored	Recording frequency
All control devices	Flow through bypass lines (or verification of valve seal)	Hourly (or monthly for valve seal)
Scrubber	Liquid flow rate or pressure drop (pH for acid scrubbers)	Every 15 minutes (once/day for pH reading)
Thermal incinerator	Combustion chamber temperature	Every 15 minutes
Condenser	Product-side outlet temperature	Every 15 minutes
Carbon adsorber (nonregenerative)*	Operating time since last replacement of adsorption media	Each replacement
Carbon adsorber (regenerative)*	1) total regeneration stream mass or volumetric flow during the carbon bed regeneration cycle(s), 2) temperature of carbon bed after regeneration, 3) temperature of carbon bed within 15 minutes of completing any cooling cycles, 4) operating time since the end of last regeneration, and 5) check for bed poisoning.	Once per regeneration cycle

* Requirement added in renewal permit

The 2002 permit modification required stack testing of several control devices that were treating streams containing five tons or more per year HAPs. The testing has since been completed and was used to establish control device parameter values corresponding to proper control device performance (i.e., the efficiency assumed in HAP emission calculations) for the control devices. For control devices treating at least one ton per year HAPs but less than five tons per year, appropriate parameter values may be based on an engineering assessment or manufacturer's recommendations. The permit requires monitoring and recording of the determined values at specified frequencies. The monitoring serves to identify periods in which the control device operated outside the range corresponding to proper control. Conditions IV.B.32 and IV.B.33 define "exceedance" and "excursion" of control device operating parameters. The permit requires that records of exceedance and excursion periods be maintained and that the information be used to adjust HAP emission calculations.

For control devices treating streams having less than one ton per year HAP (individual or in the aggregate, before control), Condition IV.B.19 of the draft renewal permit prescribes a daily verification that the control device is operating properly. The permit further requires that proper parametric values for such control devices be set according to manufacturer's recommendations or an engineering assessment for worst-case control conditions (anticipated scenario most challenging to the control unit).

The permit also includes visual inspection requirements of wastewater management units and treatment processes. Wastewater treatment HAP emissions are required to be calculated using TOXCHEM software and based on daily HAP influent concentration, temperature and flow rate values.

Recordkeeping

The permit requires extensive recordkeeping of data related to the accurate quantification of the facility's HAP emissions. Such records include:

- HAP emission factors for each manufacturing process
- Site-specific equipment component (leak) emission factors
- Number of production units per month and year for each manufacturing area
- Monthly and annual calculation of individual and total HAPs from each manufacturing area on the site, equipment components (leaks), wastewater treatment, and miscellaneous sources (sludge drying, wastewater conveyance systems, stationary internal combustion engines, lab hoods, boilers, gasoline tanks, and materials used in maintenance, repair, and construction activities (coatings, adhesives, lubricants, etc.))
- Production/operating characteristics (wastewater flow rate, HAP concentration, etc.) used as input values for process-area wastewater conveyance emissions calculations.
- MSDS for HAP-containing raw materials
- Control device downtime
- Continuous monitoring system downtime
- Performance test results
- Records of daily control device verification
- Calibration checks of and maintenance work on control devices
- LDAR-related records

Testing

The permit requires Merck to conduct stack testing within 180 days of installation of any new or replacement control device treating five tons per year or more HAPs or within 180 days of beginning to take HAP control credit on any control device treating five tons per year or more HAPs for which control was not previously claimed. Each test must be conducted according to EPA reference methods (or DEQ-approved equivalent) and under conditions that are most challenging to the control device. Operating data monitored during testing and test results must be used to establish control device parameter ranges corresponding to the control level assumed in HAP emission calculations.

A table of test methods has been included in the permit if testing is performed. The Department and EPA have authority to require testing not included in this permit if necessary to determine compliance with an emission limit or standard.

Reporting

The permit requires Merck to report its actual emissions of individual and total facility-wide HAPs each quarter. The permit also requires Merck to notify the Valley Region Director in writing each time a HAP control device is shutdown or malfunctions if the shutdown or malfunction results in HAP emissions exceeding ten pounds.

The permit further requires Merck to notify DEQ of significant modifications or significant new installations. Significant is defined in the permit as an increase of emissions of any individual HAP of one ton per year or more or of emissions of total HAPs of 2.5 tons per year or more.

Changes to this section since the 2002 modification

Originally, the synthetic minor HAP limits and supporting requirements were in the same section of the permit as the visible emissions requirements (which are also facility-wide). In the draft renewal permit, the synthetic minor HAP limits and supporting requirements are in a separate section (Section IV). Visible emissions-related conditions have been moved to Section VI of the permit.

Additionally, the following changes have been made to the synthetic minor HAP limits section (Section IV) of the permit (condition numbers refer to numbers in original modified (2002) permit):

- Condition IV.A.3 – instructions for calculating emissions during the first year following the limits' effective date have been removed, as this period has passed.
- Condition IV.B.5 (Initial Emission Factor Determination: Leaks) – deleted (requirement fulfilled)
- Conditions IV.B.7 (HCl Leak Detection) and IV.B.9 (Organic HAP Leak Detection) – Requirements for initial monitoring removed (fulfilled). Also, for IV.B.9, equipment in ethylene glycol service has been excluded (exclusion was previously approved by DEQ).
- Conditions IV.B.7, IV.B.8, and IV.B.17 (related to HCl leak detection): changed to apply to anhydrous HCL (aHCl). HCl and water mixtures (muriatic acid) do not exhibit HCl concentrations that meet leak concentration criteria (over past four years, measurements of muriatic acid components revealed a maximum of below 40 ppm, compared to threshold leak levels of 500 – 10,000 ppm). Muriatic acid components remain subject to the Leak Maintenance and Repair program (which includes visual inspections) and to reporting of any spills/discharges.
- Condition IV.B.12 (Leak Repair) – The phrase "in-service" has been added to the number of days allowed by the condition for repair of leaks (i.e., leaks must be repaired within "five in-service calendar days")
- Condition IV.B.13 (Delay of Repair) – sentence added allowing delay of repair of leaking equipment is isolated from process and taken out of HAP service.
- Conditions IV.B.16 and IV.B. 17 (Organic HAP Service and HCl Service) – definitions now specify "process" fluids (to differentiate from wastewater fluids)

- Condition IV.B.19 (Leak Emissions Calculations – First Year) – deleted (requirement fulfilled)
- Condition IV.B.21 (Leak Emission Rate Adjustment) – The portion of the condition requiring adjustment of reported emissions based on increases in detected leak rates has been moved to the "Emission Factor Adjustment" condition (IV.B.18). The remainder of Condition IV.B.21 was determined to be redundant and has been removed.
- Condition IV.B.23 (Wastewater Conveyance Systems Containing HAPs) – Specifications for calculating emissions during first year after effective date of SM limits removed, as this period has passed.
- Conditions IV.B.26 – IV.B.28 (Parametric monitoring parameters for scrubbers, condensers, and thermal oxidizers) – Monitoring device calibration frequency has been changed to the frequency recommended by the monitoring device manufacturer or every two years, whichever is more stringent.
- Condition V.E.3: a ten-pound HAP emission threshold has been added to the requirement to report control device shutdown/malfunctions o DEQ (i.e., requires reporting of any shutdown/malfunction lasting more than one hour that results in ten pounds or more HAP emissions)

The following new conditions have been added to Section IV:

- Conditions specifying parametric monitoring requirements for nonregenerative and regenerative carbon adsorbers
- Condition stating that DEQ may request further verification of wastewater treatment HAP emission calculations if actual wastewater treatment and facility-wide HAP emissions increase such that they are close to allowable levels

Facility Wide Conditions for Hazardous Air Pollutants (HAPs) – Major Source Operation

A section has been added to the renewal permit that states that Merck will become a major HAP source on January 1, 2008. Upon that date, Merck will be subject to the requirements of 40 CFR 63 Subpart GGG (Pharmaceuticals MACT) and 40 CFR 63 Subpart DDDDD (Boiler MACT), which are applicable to major HAP sources. Section V of the permit includes the specific requirements of the two MACTs as they would apply to current Stonewall Plant operations. Section V incorporates by reference the limitations, monitoring, recordkeeping, reporting, and testing requirements of 40 CFR 63 Subpart GGG. The specific requirements are included in tabular form as a permit attachment (Attachment B to the permit). Section V also includes the initial notification requirement of Subpart DDDDD (the only requirement from the rule applicable to Merck).

Section V also includes an allowance for Merck to postpone its transition to major-source status by providing a written notification of its intent to do so. The notification must be provided at least 30 days prior to the scheduled transition date (January 1, 2008). Providing the notice moves the transition date forward by six months (July 1, 2008). Merck can again choose to

delay its transition to major-source for another six-month period by providing another notice at least 30 days before July 1, 2008. Merck may continue to thus delay its transition, in six-month intervals, for the remainder of the permit term. If Merck fails to provide notification, its transition to major-source status (and applicability of the MACT requirements) will become effective upon the next scheduled transition date.

Upon transition to HAP major-source status, the requirements of Section V will supersede the requirements of Section IV (synthetic minor HAP operation).

Limitations

Section V incorporates the emission standards for process vents, storage tanks, equipment leaks and wastewater in 40 CFR 63 Subpart GGG, specifically 40 CFR 63.1253 – 1256. The emission standards and limitations are detailed in Attachment B to the permit. The process operations subject to these standards include: Carbidopa, Indinavir, MK-476, Central Solvent Recovery, Cilastatin, Imipenem, sodium bicarbonate, Primaxin for Recovery, MK-991, Dorzolamide, and wastewater treatment correlated with Unit Reference Numbers 11, 21, 22, 41, 42, 72, 73, 74, 75, 81, 23, and F, respectively.

The permit requires Merck to keep a current list of affected operating areas subject to the standards, monitoring, recordkeeping, reporting, and testing requirements of 40 CFR 63 Subpart GGG.

Management of Change

The permit includes language that facilitates certain minor process changes at the facility without requiring a permit modification. The "Management of Change" portion of Section V is structured after EPA's Management of Change approach described in the preamble to 40 CFR 63 Subpart GGG. It allows certain changes at the facility, providing that specified "replicable procedures" are followed. Merck has identified the following replicable procedures, all from 40 CFR 63 Subpart GGG, as those that will govern assessment of any changes implementing Management of Change:

Table 6. Replicable operating procedures to be used for changes under Management of Change provisions

Procedure	40 CFR Part 63 Citation
Calculating uncontrolled emissions from process vents--equations for eight types of operations	63.1257(d)(2)(i)(A) through (H)
Calculating controlled emissions from process vents discharged through a condenser--equations for eight types of operations	63.1257(d)(3)(i)(B)(*1*) through (*8*)
Equations for determining whether an existing vent is subject to 98% control	63.1254(a)(3)(i)
Maximum true vapor pressure for determining storage tank applicability.	63.1251 definition
EPA performance test methods and calculations	63.1257(a)(2), (a) (3), (b)(1) through (8), and (b)(10)(i) through (iii)

All but one of the proposed replicable operating procedures (ROPs) are considered by EPA as replicable as written in 40 CFR 63 Subpart GGG. One proposed ROP (the definition of maximum true vapor pressure in 40 CFR 63.1251 for determining storage tank applicability) is considered by EPA to be a "potentially replicable operating procedure" that can be established through permitting where approved by the permitting authority and subject to review by EPA and the public. DEQ proposes that the proposed maximum true vapor pressure definition in 40 CFR 63.1251 be established as a ROP in Merck's Title V renewal permit. DEQ will request that EPA review the proposed ROP during EPA's review of the draft/proposed renewal permit. The public notice for the renewal permit will also highlight the proposed ROP.

Changes allowed under the Management of Change approach include shifting/reconfiguring process equipment and eliminating process equipment, provided that the new configuration does not exceed the worst-case operating conditions of the control devices as demonstrated in the Notification of Compliance Status Report (NOCSR) required by 40 CFR 63.1260(f) and that the new configuration complies with all applicable requirements under 40 CFR 63 Subpart GGG. In accord with EPA Management of Change guidance (Federal Register Volume 63, Number 182, September 21, 1998), new equipment allowed to be added under the Management of Change provisions are limited to the following:

- New condensers that are like-kind replacements for those currently incorporated into the permit through the NOCSR;
- Like-kind replacement of permitted process equipment that is being retired, where the replacement equipment is functionally equivalent to and provides no greater production capacity than the equipment being retired. New process equipment that is replacing equipment that will continue in service elsewhere at the site may not be added under

these provisions;

- Process equipment that already exists on-site but is not in current service. Such equipment shall be specifically identified in the permit in terms of its type and capacity.

Equipment added under Management of Change terms shall meet all provisions of the permit and of 40 CFR 63 Subpart GGG governing its operation, including the requirement to stay within the approved performance capabilities or capacity limitations (based on the NOCSR) of the control device to which its emissions are routed.

The permit requires all changes to be listed in an on-site implementation log (OSIL) that details each operating scenario and the applicable compliance requirements, including the following:

- A description of the process and the type of process equipment used.

- An identification of related process vents and their associated emissions episodes and durations, wastewater points of determination (PODs), and tanks

- The applicable control requirements of Subpart GGG, including the level of required control.

- The control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device.

- The process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s).

- The applicable monitoring requirements of Subpart GGG and any parametric level that assures compliance for all emissions routed to the control or treatment device.

- Calculations and engineering analyses required to demonstrate compliance, including the basis for such calculations and analyses.

- A verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed.

The permit requires Merck to notify the Valley Region Director within 30 days of any changes to applicability of emission standards, monitoring requirements, recordkeeping requirements, reporting requirements, and testing requirements resulting from new or modified HAP sources (according to Management of Change allowances) on the site. (It should be noted that preconstruction review requirements under 40 CFR 63.5 would apply to a new Pharmaceutical Manufacturing Process Unit (PMPU) if it has potential HAP emissions above major-source levels (10 tons/yr of a single HAP or 25 tons/year combined HAPs)). It also

requires Merck to submit quarterly reports indicating any changes in operating scenarios since the most recent report.

The Management of Change provisions are not intended to limit changes that may be made at the facility, but rather to designate certain changes as ones that do not require the permit to be modified or reopened. Other process modifications or installations that are not specifically identified under Management of Change provisions may be subject to modification or reopening procedures outlined in 9 VAC 5 Chapter 80, Article 1 (Federal Operating Permits for Stationary Sources). According to 9 VAC 5-80-80 C.2, Merck would be required to file a complete application to obtain a permit revision within 12 months after the commencement of operation of the new or modified process, unless the Title V permit prohibits the construction or change in operation. If the permit prohibits the construction or change in operation, Merck would be required to obtain a permit revision before the new or modified process commenced operation. As noted in the preceding paragraph, if the process modification or installation is itself a new Pharmaceutical Manufacturing Process Unit (PMPU) having potential HAP emissions above major-source levels (10 tons/yr of a single HAP or 25 tons/year combined HAPs), the preconstruction review requirements under 40 CFR 63.5 would apply.

Monitoring

The permit incorporates all monitoring requirements for process vents, storage tanks, equipment leaks and wastewater in Subpart GGG, specifically 40 CFR 63.1258. The monitoring requirements are detailed in Attachment B to the permit.

Recordkeeping

The permit requires Merck to record and retain all information necessary to determine that the operation of the process vents, storage tanks, equipment leaks and wastewater system is in compliance with 40 CFR 63.1253 –1256 (which includes the recordkeeping requirements detailed in Attachment B to the permit).

Reporting

The permit requires Merck to meet all applicable reporting requirements for process vents, storage tanks, equipment leaks and wastewater subject to 40 CFR 63.1253 – 1256 (which includes the reporting requirements detailed in Attachment B to the permit). The permit also includes the requirement for Merck to provide Initial Notification (due 120 calendar days after becoming a major HAP source) for the Boiler MACT (40 CFR 63 Subpart DDDDD).

Testing

The permit requires Merck to conduct all required testing in accordance with 40 CFR 63.1257 (which includes the testing requirements detailed in Attachment B to the permit). Previous testing of control devices conducted in accordance with procedures approved by the DEQ as a synthetic minor source for HAPs, but subsequently subject to 40 CFR 63.1257 as a

major HAP source for HAPs, may meet these requirements upon case-by-case approval by the Director, Valley Region.

Facility-Wide Conditions – Visible Emissions

Requirements related to visible emissions were included in Section IV of the original Title V (and modified Title V) permit. In the renewal permit, these requirements have been moved to Section VI. Other than relocating the terms in the permit, there have been no other changes to the conditions since the 2002 modification.

Limitations

The PSD permit did not contain any visible emission limitations. Therefore, the following requirements have been added to the permit:

9 VAC 5-40-80: Standard for Visible Emissions

9 VAC 5-50-80: Standard for Visible Emissions.

Monitoring

40 CFR 60.49b(u)(1)(ii), a site-specific monitoring requirement in NSPS Subpart Db, requires Merck to operate a continuous emissions monitoring system or a predictive emissions monitoring system for visible emissions from the natural gas-fired boilers. This requirement has been incorporated into the Title V permit.

The PSD permit did not address visible emission requirements and those limitations had to be added as part of the Title V permit. The visible emission limit established in the permit was established for all process unit stacks with the potential to emit particulate matter. Merck is required to perform monthly visible emission checks on each process unit stack that has the potential to emit particulate matter above "insignificant activity" levels. Those stacks that do not emit particulate matter will most likely be pure VOC streams, meaning that no visible emissions are expected. Emission units that have uncontrolled particulate emissions below the level of Title V insignificant activity (9 VAC 5-80-710 et seq.) are listed in Attachment A to the permit. Merck is not required to perform visible emissions observations on the listed stacks.

If visible emissions are present on any of the stacks that are observed, a six-minute visible emission evaluation must be performed unless corrective action can be taken such that the stack is returned to no visible emissions. If during the six minutes, any violations of the 20% opacity standard are noted, a one-hour visible emission evaluation is required to demonstrate compliance with the standard. If 12 monthly inspections are performed on any given stack, and no visible emissions are present, then the visible inspections may be performed quarterly. However, as soon as visible emissions are noted during a quarterly inspection, the inspections must then be performed monthly again. This requirement satisfies the periodic monitoring requirement for the opacity standards on the process unit stacks with the potential to emit particulate matter.

Recordkeeping

Merck will be required to keep records as required for the opacity monitor on the natural gas-fired boilers and the visible emission evaluations on process unit stacks with the potential to emit particulate matter.

Testing

The permit does not require source tests. A table of test methods has been included in the permit if testing is performed. The Department and EPA have authority to require testing not included in this permit if necessary to determine compliance with an emission limit or standard.

Reporting

The permit requires Merck to notify DEQ of any equipment or process changes to the activities listed in Attachment A to the permit resulting in uncontrolled emissions above the insignificance level. It also requires that an up-to-date log be kept on site at all times listing units meeting the insignificance level.

Administration of PSD (Project XL) Permit

The following Sections of the PSD permit deal only with the administration of the PSD permit. As such, they have been included in a section of the Title V permit that has been devoted to Administration of the PSD permit (Section VII).

Section 6	-	Periodic Review of the PSD Permit
Section 7	-	Duration of the PSD Permit
Section 8	-	Termination of the PSD Permit
Section 9	-	Inspection and Entry
Section 10	-	Reservation of Rights
Section 11	-	Transfer of Ownership
Section 12	-	Definitions for Terms in the PSD Permit

Streamlined Requirements

The following Section was not incorporated into the Title V permit because the requirements have been completed. Please note that section numbers refer to those found in the PSD permit, a copy of which is included as Attachment B.

Section 8.1.3 - The powerhouse conversion has been completed.

The only change made to this section of the permit since from the original Title V permit is that the names of the Project XL signatories have been deleted from Table VIII of the permit. Signatories are now identified by title only. This is consistent with changes to the XL PSD permit agreed to by the stakeholders at the five-year periodic review meeting on July 28, 2005.

Compliance Plan

Provisions have been added to the Title V renewal permit (Section VIII) that are at least as stringent as the requirements in the July 8, 2005 Consent Order between DEQ and Merck & Co., Inc. The Consent Order is attached (Attachment E). Several requirements of the order have been fulfilled (Items 5, 6, 9, and 10 of Appendix A of the order); those provisions are not reflected in the Title V compliance plan. The consent order (and the Title V renewal permit's compliance plan) requires Merck to:

- operate and monitor certain control devices in the Carbidopa process according to listed specifications;
- upgrade the site's chemical sewer system such that it meets the emission suppression requirements of the Pharmaceutical MACT at 40 CFR 63.1256 by July 15, 2007;
- install a fixed roof on a wastewater treatment mix tank (TA-115) by July 15, 2007;
- conduct an engineering assessment to determine the impact of the additional HAP loading (resulting from the sewer upgrade and the covered mix tank) on the biological treatment unit of the Stonewall Plant's WWTP, within 180 days of completion of the sewer upgrade and covering the tank;
- sample and analyze HAP concentrations and characteristics of flow at the WWTP influent (for any HAP for which WWTP control credit is claimed);

The permit also requires Merck to submit monthly reports of sitewide individual and total HAP emissions and daily WWTP influent sampling and analysis composite results. The Compliance Plan section of the draft Title V renewal permit includes terms that are at least as stringent as the requirements from Appendix A of the 7/8/05 Consent Order.

Compliance with State and Federal Regulations and Air Permits Under PSD (Project XL) Permit

Sections 2 and 3 of the PSD permit have been included in Section X of the Title V permit as the means for complying with applicable state and federal regulations.

Streamlined Requirements

Parts of the following Sections were not incorporated into the Title V permit because the requirements have been completed. Please note that section numbers refer to those found in the PSD permit, a copy of which is included as Attachment B.

Sections 2.1, 2.2, and 2.3 - The powerhouse conversion has been completed.
Section 3.1 - List of preconstruction permits replaced by PSD permit.
Section 4.3.2 - PM-10 cap adjustment has been completed.

PROJECT XL PSD PERMIT CHANGES (FIVE-YEAR REVIEW)

Concurrently with processing the Title V renewal permit, the PSD permit is undergoing modification. The modification is to incorporate changes agreed to by project stakeholders at the five-year stakeholder review meeting held July 28, 2005. The changes to the PSD permit include the following (section numbers refer to the PSD permit):

- *Section 4.1: Reporting Tiers:* addition of actual emission thresholds for SO_2 and NO_x to the three-tiered monitoring plan such that more stringent monitoring may be triggered based on actual emissions of SO_2 or NO_x and not just based on actual total emissions. Under the proposed change, Tier 1 monitoring applies if actual total criteria pollutant emissions for the last 12 months are greater than 0 and less than 75% of the total emissions cap and actual emissions of SO_2 or NO_x for the last 12 months are greater than 0 and less than 75% of the individual respective emission caps. Tier 2 monitoring applies when actual total criteria pollutant emissions for the last 12 months are equal to or greater than 75% and less than 90% of the total emissions cap or actual emissions of SO_2 or NO_x for the last 12 months are equal to or greater than 75% and less than 90% of the individual respective emission caps. Tier III monitoring applies if actual total criteria pollutant emissions for the last 12 months are equal to or greater than 90% of the total emissions cap or actual emissions of SO_2 or NO_x for the last 12 months are equal to or greater than 90% of the individual respective emission caps. If a higher monitoring level is triggered by the SO_2 or NO_x subcap, only monitoring relevant to the pollutant subcap (as identified in Table 4.2 of the XL permit) is affected.

- *Section 4.4: Monthly Requirements:* revise due date for monthly calculations specified in Table 4.2 of the XL permit from one month to two months after the end of the rolling 12-month period being evaluated. This change was proposed by Merck to make XL calculation requirements consistent with those for HAPs in Merck's Title V permit.

- *Section 4.11.1: HAP Monitoring and Emission Testing Requirements Under CAA Section 112(d):* addition of language allowing that Merck's Title V HAP monitoring for a particular control device shall constitute compliance with XL monitoring, where such Title V monitoring is more stringent than the applicable XL monitoring.

- *Miscellaneous changes throughout permit,* to include
    - deletion of references to Sludge Incinerator (permanently shutdown);
    - designation of individual pollutant, where applicable, for each monitoring, recordkeeping, and reporting requirement in Table 4.2;

- revision of Table 4.2 Tier III requirement for control equipment such that stack testing shall be conducted to confirm performance, unless such testing is infeasible, in which case other engineering assessments may be used upon DEQ approval;
- addition of RE-3501 (new Carbidopa thermal oxidizer) to item F.18 of Table 4.2;
- addition of phrase "most current update" to reference to AP-42 5th edition in Table 4.3
- removal of names of individual signatory representatives (representatives to be identified through titles only); and
- regulatory citations have been updated throughout permit.

All changes are reflected in the Title V renewal permit.

The PSD permit will be modified according to the provisions of Merck's site-specific variance (9 VAC 5 Chapter 190). Stakeholders were given the opportunity to review and comment on the draft modified PSD permit from July 10 through July 24, 2006. No comments on the draft modified permit were received from the stakeholders. Public notice will be provided simultaneously for the draft modified PSD permit and the draft Title V renewal permit. This permit amendment will be issued contemporaneously with the proposed Title V permit.

COMPLIANCE ASSURANCE MONITORING

The Compliance Assurance Monitoring (CAM) Rule at 40 CFR 64 is not applicable to Merck's Stonewall Plant.

For criteria pollutants, the monitoring required by the Project XL PSD permit constitutes alternate compliance with CAM. Section 3.4.2.a of the XL PSD permit states that "Monitoring requirements specified in Section 4 of the PSD permit shall constitute compliance with any applicable monitoring requirements in 40 CFR 71.6(a)(3) and 9 VAC 5-80-110 E that would be applicable to provisions of this permit." 40 CFR 71.6(a)(3)(A) includes "All emissions or test methods required under the applicable requirements, *including any procedures and methods promulgated pursuant to sections 114(a)(3) or 504(b) of the Act*" (emphasis added). Section 114(a)(3) of the Act is the specific statutory basis for promulgation of the CAM Rule. The CAM Rule is also incorporated into 40 CFR 71.6(a)(3) and 9 VAC 5-80-110 E. Accordingly, the monitoring provisions of the XL PSD permit constitute alternate compliance with the CAM Rule.

The applicability of the CAM Rule to HAP-controlling devices was considered in evaluating the renewal application. The only emission limits for HAPs are the facility-wide synthetic minor HAP limits of 9.9 tons/yr (for each individual HAP) and 24.9 tons/yr (for total HAPs). Guidance received from EPA Region 3 on the applicability of CAM to Merck's SM HAP limits indicated that such facility-wide limits are not appropriate for CAM and therefore control devices used to meet such limits are not subject to CAM. Rather, compliance with such "mass accumulation" limits is more appropriately assessed using an extensive monitoring and recordkeeping

combination such as that which is established in Section IV of the Title V permit for the SM HAP limits. It should be noted that the monitoring already established in the Title V permit for larger HAP control devices would meet CAM criteria (e.g., parameters are recorded continuously or every 15 minutes).

GENERAL CONDITIONS

The permit contains general conditions required by 40 CFR Part 70 and 9 VAC 5-80-110, that apply to all Federal operating permit sources. These include requirements for submitting an annual compliance certification report. The permit also requires notification of deviations from permit requirements or any excess emissions, including those caused by upsets, within four daytime business hours.

Several of the General Conditions that are normally included in Virginia's Title V operating permits are not applicable to Merck – either because the Variance (9 VAC 5 Chapter 190) explicitly states that they are not applicable or because they contradict conditions in the PSD permit. The following General Conditions have been omitted from Merck's Title V operating permit. Please note that condition numbers refer to those found in the Title V operating permit boilerplate.

Omitted because they are not applicable:

Condition C: Recordkeeping and Reporting

Condition O: Startup, Shutdown, and Malfunction

Condition Q: Inspection and Entry Requirements

Omitted because they contradict with conditions in the PSD permit:

Condition Z: Changes to Permits for Emissions Trading

Condition AA: Emissions Trading

STATE ONLY APPLICABLE REQUIREMENTS

Merck did not identify any state-only enforceable requirements in their application, and all requirements in the PSD permit are federally enforceable. Therefore, no state-only applicable requirements have been included in the permit.

FUTURE APPLICABLE REQUIREMENTS

As detailed above, upon transition to major-source status Merck will be subject to the Pharmaceuticals MACT (40 CFR 63 Subpart GGG) and initial notification requirements of the Boiler MACT (40 CFR 63 Subpart DDDDD). Transition to major-source status will take place on January 1, 2008, unless Merck opts to delay such transition and provides the required notification.

INAPPLICABLE REQUIREMENTS

In its renewal application, Merck identified the following regulations as inapplicable to its operations.

- 40 CFR 60 Subpart III (NSPS for VOC Emissions from the Synthetic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Process): Applicable to air oxidation unit processes manufacturing regulated (listed) chemicals; Stonewall Plant does not operate an air oxidation unit process.
- 40 CFR 60 Subpart RRR (NSPS for VOC Emissions from SOCMI Reactor Processes: Applicable to specified reactor processes manufacturing regulated (listed) chemicals; Stonewall Plant does not operate the affected reactor processes (rule exempts any reactor process designed and operated as a batch operation).
- 40 CFR 60 Subpart VV (NSPS for Equipment Leaks of VOC from the SOCMI): Applicable to SOCMI facilities that produce one or more chemicals listed in 40 CFR 60.489; Stonewall Plant does not produce listed chemicals.
- 40 CFR 60 Subpart NNN (NSPS for VOC from SOCMI Distillation Processes): Applicable to SOCMI facilities that produce one or more chemicals listed in 40 CFR 60.489; Stonewall Plant does not produce listed chemicals.
- 40 CFR 60 Subpart YYY (NSPS for VOC from SOCMI Wastewater Emissions): Applicable to SOCMI facilities that produce one or more chemicals listed in 40 CFR 60.489; Stonewall Plant does not produce listed chemicals.

The regulations have been included as inapplicable requirements in the renewal permit.

It should be noted that the following regulation is not applicable to the Stonewall Plant (this was potentially applicable after Merck's transition to major HAP source status):

40 CFR 63 Subpart ZZZZ (NESHAP for Reciprocating Internal Combustion Engines (RICE)): According to 40 CFR 63.6590(b)(3), existing emergency stationary RICE do not have to meet the requirements of 40 CFR 63 Subpart ZZZZ or 40 CFR 63 Subpart A and states that no initial notification is required. Each unit at Stonewall Plant that is rated above 500 bhp (i.e., each RICE) is used for emergency purposes and therefore meets the criteria of 40 CFR 63.6590(b)(3).

INSIGNIFICANT EMISSION UNITS

Merck identified several insignificant emission units in its application. The units have been included in the permit as insignificant activities.

The insignificant emission units are presumed to be in compliance with all requirements of the Clean Air Act as may apply. Based on this presumption, no monitoring, recordkeeping or reporting shall be required for these emission units in accordance with 9 VAC 5-80-110.

Insignificant emission units include the following:

Table 7. Insignificant emission units

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
CE-511	Centrifuge operations	9 VAC 5-80-720 B	PM/PM-10
RE-506	Sodium bisulfate charge	9 VAC 5-80-720 B	PM/PM-10
RE-508	NaCN charge	9 VAC 5-80-720 B	PM/PM-10
RE-601/RE-601A	Hydrazinonitrile charge	9 VAC 5-80-720 B	PM/PM-10
TA-73	Breathing and filling emissions (HCl)	9 VAC 5-80-720 B	PM/PM-10*
TA-701	Batch processing (HCl present)	9 VAC 5-80-720 B	PM/PM-10*
ST-604 TA-608 VJ-609	Batch processing (HCl present)	9 VAC 5-80-720 B	PM/PM-10*
TA-621	HCl distillates	9 VAC 5-80-720 B	PM/PM-10*
TA-606	Filling with washes containing HCl	9 VAC 5-80-720 B	PM/PM-10*
TA-710	Filling emissions (HCl present)	9 VAC 5-80-720 B	PM/PM-10*
TA-704	Disodium EDTA charge	9 VAC 5-80-720 B	PM/PM-10
TA-703 DC-703	Carbon charge	9 VAC 5-80-720 B	PM/PM-10
DR-913	Batch drying	9 VAC 5-80-720 B	PM/PM-10
MI-916	Milling	9 VAC 5-80-720 B	PM/PM-10
BN-917	Blending	9 VAC 5-80-720 B	PM/PM-10
FD-850 DC-836	Packaging from FD-850	9 VAC 5-80-720 B	PM/PM-10
SCR-601	Buggy charge to ST-901	9 VAC 5-80-720 B	PM/PM-10
FD-850 DC-850	Batch drying	9 VAC 5-80-720 B	PM/PM-10
CE-821	Centrifuge operations	9 VAC 5-80-720 B	PM/PM-10
DR-914	Batch drying	9 VAC 5-80-720 B	PM/PM-10
DI-910	Charge of material recovered from PF-929 A/B	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
Buggy	Centrifuge buggy charge to ST-901	9 VAC 5-80-720 B	PM/PM-10
DR-713	Drying of Carbidopa seed	9 VAC 5-80-720 B	PM/PM-10
TA-1108 GB-1108	Picolyl chloride charge	9 VAC 5-80-720 B	PM/PM-10
FD-1206	Batch filtration	9 VAC 5-80-720 B	PM/PM-10
TOU-2542/SCR-2546	Combustion of natural gas	9 VAC 5-80-720 B	PM/PM-10
HP-2604	Sodium sulfate charge Sodium chloride charge	9 VAC 5-80-720 B	PM/PM-10
HP-2606	Citric acid charge Oxoester charge	9 VAC 5-80-720 B	PM/PM-10
HP-2612	Sodium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
HP-2614	Potassium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
HP-2616	Sodium sulfite charge	9 VAC 5-80-720 B	PM/PM-10
HP-2721	Lithium hydroxide charge	9 VAC 5-80-720 B	PM/PM-10
HP-2721A	Rework charge	9 VAC 5-80-720 B	PM/PM-10
TA-2604	Sodium sulfate charge Sodium chloride charge	9 VAC 5-80-720 B	PM/PM-10
TA-2612	Sodium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
TA-2614	Potassium bicarbonate charge	9 VAC 5-80-720 B	PM/PM-10
TA-2616	Sodium sulfite charge	9 VAC 5-80-720 B	PM/PM-10
BD-1552	Packaging batches	9 VAC 5-80-720 B	PM/PM-10
CE-1200	Cake discharge to bin	9 VAC 5-80-720 B	PM/PM-10
CE-1400	Cake discharge to bin	9 VAC 5-80-720 B	PM/PM-10
GB-2242	cis-Aminoindanol charge	9 VAC 5-80-720 B	PM/PM-10
RE-2242	cis-Aminoindanol charge Monoaldehyde charge	9 VAC 5-80-720 B	PM/PM-10
TA-2721	Sodium bicarbonate charge Filter aid charge Ammonium acetate charge Lithium hydroxide charge	9 VAC 5-80-720 B	PM/PM-10
TA-2606	Citric acid charge	9 VAC 5-80-720 B	PM/PM-10
TA-1277	Monohydrate seed charge	9 VAC 5-80-720 B	PM/PM-10
TA-1263	Monohydrate seed charge	9 VAC 5-80-720 B	PM/PM-10
RE-1267	Boc-piperazine charge Vacumax discharge	9 VAC 5-80-720 B	PM/PM-10
RE-1269	Boc-piperazine charge Vacumax discharge	9 VAC 5-80-720 B	PM/PM-10
RE-1425	Processing emissions (HCl)	9 VAC 5-80-720 B	PM/PM-10*
CR-1205	Palladium charge	9 VAC 5-80-720 B	PM/PM-10
CR-1281	Seed charge	9 VAC 5-80-720 B	PM/PM-10
GB-2270	Sodium borohydride charge	9 VAC 5-80-720 B	PM/PM-10
RE-2275	$CaCl_2$ charge for brine make-up	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
TA-106	Nutrient charges	9 VAC 5-80-720 B	PM/PM-10
F-14	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-15	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-16	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-17	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-3	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-4	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-5	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-6	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-7	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-8	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-9	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-10	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-11	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-12	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-13	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-14	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-15	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-16	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-27	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-28	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-29	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-30	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-31	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-32	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-34	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-1	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-2	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-3	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-4	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-5	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-10	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-11	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
F-12	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-17	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-18	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-24	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-25	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-26	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-1	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
G-2	Fermentation	9 VAC 5-80-720 B	VOC / PM-10
RE-221	Sodium carbonate charge	9 VAC 5-80-720 B	PM/PM-10
TA-800	Non-sterile Cilastatin charge	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
FD-845 DC-845 VP-1075 VP-1075-1 VJ-472C	Batch drying (roughing phase and final phase)	9 VAC 5-80-720 B	PM/PM-10
MI-855	Milling operations	9 VAC 5-80-720 B	PM/PM-10
GB-860	Product packaging	9 VAC 5-80-720 B	PM/PM-10
VP-1040	Batch drying (roughing phase)	9 VAC 5-80-720 B	PM/PM-10
VP-1041	Batch drying (final phase)	9 VAC 5-80-720 B	PM/PM-10
VP-1050	Batch drying (roughing phase)	9 VAC 5-80-720 B	PM/PM-10
VP-1051	Batch drying (final phase)	9 VAC 5-80-720 B	PM/PM-10
GB-760	Product packaging	9 VAC 5-80-720 B	PM/PM-10
GB-765	Product packaging	9 VAC 5-80-720 B	PM/PM-10
TA-714	Non-sterile Imipenem charge	9 VAC 5-80-720 B	PM/PM-10
MI-900	Milling operations	9 VAC 5-80-720 B	PM/PM-10
GB-930	Product packaging	9 VAC 5-80-720 B	PM/PM-10
TA-725	Charge Cilastatin/Imipenem blended mixture for recovery	9 VAC 5-80-720 B	PM/PM-10
WS-508	Subdivision booth	9 VAC 5-80-720 B	PM/PM-10
FD-9900 VP-9950	Batch drying	9 VAC 5-80-720 B	PM/PM-10
WS-9900	Subdivide pure intermediate Subdivide phenyl boric acid Subdivide OS1 intermediate Subdivide samples Subdivide bulk API	9 VAC 5-80-720 B	PM/PM-10
GB-9605	Charge crude intermediate Charge proline Charge phenyl boronic acid Charge OS1 intermediate Charge seed	9 VAC 5-80-720 B	PM/PM-10
ST-9800	Charge crude intermediate Charge proline Charge sodium acetate	9 VAC 5-80-720 B	PM/PM-10
EF-9075	Subdivide silica Subdivide proline Subdivide sodium acetate Subdivide kromasil Subdivide sodium metabisulfate	9 VAC 5-80-720 B	PM/PM-10
TA-9754 funnel TA-9754	Charge silica	9 VAC 5-80-720 B	PM/PM-10

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
ST-9600	Charge pure intermediate Charge phenyl boronic acid Charge OS1 intermediate Charge seed	9 VAC 5-80-720 B	PM/PM-10
BT-9615	Charge triflic acid Charge 2N HCl	9 VAC 5-80-720 B	PM/PM-10*
TA-9700	Charge sodium metabisulfite	9 VAC 5-80-720 B	PM/PM-10
ST-9700	Charge sodium metabisulfite	9 VAC 5-80-720 B	PM/PM-10
FD-9980	Batch drying	9 VAC 5-80-720 B	PM/PM-10
Antibiotic filling line	Vial filling	9 VAC 5-80-720 B	PM/PM-10
Antibiotic blending	Powder consolidation	9 VAC 5-80-720 B	PM/PM-10
MX-121	Blending	9 VAC 5-80-720 B	PM/PM-10
HO-122	Hopper	9 VAC 5-80-720 B	PM/PM-10
HB-122	Pregnant chute	9 VAC 5-80-720 B	PM/PM-10
MX-185	Blending	9 VAC 5-80-720 B	PM/PM-10
HO-221	Hopper	9 VAC 5-80-720 B	PM/PM-10
HO-201	Hopper	9 VAC 5-80-720 B	PM/PM-10
IBC for MI-125	Filling of intermediate bulk container	9 VAC 5-80-720 B	PM/PM-10
EM-201	Encapsulator	9 VAC 5-80-720 B	PM/PM-10
EM-202	Encapsulator	9 VAC 5-80-720 B	PM/PM-10
EM-221	Encapsulator	9 VAC 5-80-720 B	PM/PM-10
Lakso filler	Bottle filling	9 VAC 5-80-720 B	PM/PM-10
Crixivan house vacuum	Equipment cleanup activities	9 VAC 5-80-720 B	PM/PM-10
RB-331	Magnesium stearate charge	9 VAC 5-80-720 B	PM/PM-10
RB-332	Magnesium stearate charge	9 VAC 5-80-720 B	PM/PM-10
IBC (after batch transfer from RC-330 & 333)	Magnesium stearate charge	9 VAC 5-80-720 B	PM/PM-10
TA-210	Opadry II charge	9 VAC 5-80-720 B	PM/PM-10
CM-233	Tablet compressing	9 VAC 5-80-720 B	PM/PM-10
CM-234	Tablet compressing	9 VAC 5-80-720 B	PM/PM-10
CP-238	Film coating	9 VAC 5-80-720 B	PM/PM-10
CP-249	Film coating	9 VAC 5-80-720 B	PM/PM-10
TA-250/255		9 VAC 5-80-720 B	PM/PM-10
LTE-125	Low Temperature Economizer	9 VAC 5-80-720 B	PM/PM-10
LTE-127	Low Temperature Economizer	9 VAC 5-80-720 B	PM/PM-10
General	HAPs for miscellaneous coatings	9 VAC 5-80-720 B	HAPs
General	Liquid petroleum storage tanks	9 VAC 5-80-720 B	VOC / HAPs

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)
B-7, B-8	Natural gas combustion - boilers	9 VAC 5-80-720 B	PM/PM-10

* Recognized as PM/PM-10 for purposes of visible emissions monitoring.

CONFIDENTIAL INFORMATION

The permittee provided both a confidential and public copy of its renewal application. The application included a "showing" justifying confidential treatment of the application. No part of the renewal permit itself has been designated confidential.

PUBLIC PARTICIPATION

A public notice regarding the draft permit will be placed in the Daily News Record, Harrisonburg, Virginia, on August 12, 2006. EPA will be sent a copy of the draft permit and notified of the public notice on the same date and will concurrently review the draft permit as a proposed permit. West Virginia, the only affected state, will be sent a copy of the public notice in a letter on the same date. All persons on the Title V mailing list were sent a copy of the public notice by either electronic mail or in letters on August 11, 2006. The 30-day public comment period is from August 13, 2006 through September 12, 2006.

The public notice includes an opportunity for public comment on the draft Project XL PSD permit, which is being modified simultaneously with the renewal of the Title V permit.

ATTACHMENTS

A – Supporting documentation for concurrent draft modification of Project XL PSD permit

B – Project XL PSD permit dated January 7, 1998 (administratively modified August 8, 2001 and modified xx/xx/xx)

C- Federal rulemaking for Stonewall Plant Project XL permit

D- State variance for Stonewall Plant Project XL permit (9 VAC 5 Chapter 190)

E – Consent Order dated July 8, 2005